

STATEMENT

The present invention provides a method for the preparation of ready to use solid support for rapid ELISA requiring much less time for preparing and reconstituting the said solid support having enhanced storage stability at both room temperature and cold conditions. This enables the method for the preparation of solid support of the present invention to be novel and inventive.

Applicant has gone through the written opinion of the International Search Authority and observe that:

1. Novelty of claims 1 to 19 has been acknowledged within the sense of Art. 33(2) of PCT.
2. Industrial applicability of claims 1 to 20 has been acknowledged.
3. In the light of Documents D₁ to D₉ inventive step of claims 1 to 20 is not established within the sense of Art.33(3) of PCT.

In this context, Applicant believes that the ready to use solid support for rapid ELISA has been referred to only in Document D₃, which is the closest prior art for the present invention. Also, Applicant wants to bring to the notice differences existing between their invention and the invention described in Document D₃ as enumerated herein below:

- a). In the prior art solid support for ELISA, the primary molecules (first antibody) used is not stabilized, whereas it is stabilized in the solid support of the present invention. This difference imparts to enhanced shelf life for the ready to use solid support of present invention on storing at both room temperature and 4°C respectively.
- b). Use of stabilizer in the process of present invention preserves primary molecule (first antibody) used., **whereas use of blocking agent in the prior art only blocks the unbound parts of the well present in the solid support.**
- c). Reconstitution of solid support is performed using water in both present invention and Document D₃. However, the reconstitution time taken for the solid support of present invention is one sixth of the time taken for the solid support referred to in Document D₃.
- d). Drying or lyophilization is not required after the addition of first antibody to the solid support in the present invention, which enables the process for the preparation of solid support to be less cumbersome and time consuming compared to the preparation of solid support of prior art.
- e). Second and third antibodies are added simultaneously in the preparation of ready to use solid support of present invention which is not the case with prior art processes..The simultaneous addition of antibodies contributes to significant reduction in the process time.
- f). In the process referred to in D₃ document (Example 2, Step 4) teaches introduction of cold sample dilution medium into the frozen coated plate. It appears that the total process adapted in document D₃ is performed under cold conditions, whereas the process of present invention can be effectively even at room temperature.

- g) The total time taken for the process to obtain ready to use solid support of present invention is about 24-30 hours whereas the process reported in the D₃ document to obtain ready to use ELISA plate will be around 60 hours.
4. Ref. Item VIII : Claims 19-20 do not meet the requirements of Art. 6 PCT because the subject-matter for which protection is sought is not defined at all (the solid support may be anyone used in a common immunoassay). For this reason, it is not possible to carry out a meaningful search embracing the whole scope of the claims.

Claims 19 & 20 (old numbers) have been suitably amended and re-numbered as claims 18 & 19 respectively to comply with the requirements of Art.6 PCT.

The above facts establish that ready to use solid support of the present invention is superior to the solid support reported in the prior art as far as shelf life and preparation time is concerned. This contributes to an added advantage of the present invention over the prior art invention.

The Applicant requests consideration of amended claims along with above comments.